Your High-Alert Medication List Is Relatively Useless Without Associated Risk-Reduction Strategies

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PROBLEM: Have you ever watched the 1993 movie *Groundhog Day*? Bill Murray plays Phil Connors, a television news reporter who finds himself reliving the same day over and over again—a much-hated assignment covering the annual Groundhog Day event in Punxsutawney, Pennsylvania. Well, at times it feels like Groundhog Day when we hear about the same types of errors happening over and over again. Another patient with diabetes receives a fivefold overdose of U-500 insulin after a nurse draws the dose into a U-100 syringe, and a double check by another nurse fails to detect the error. Another hospitalized patient experiencing pain receives an overdose of intravenous (IV) HYDROmorphone after a physician prescribes the IV dose in the same amount as the oral dose the patient had been taking at home, and neither the pharmacist nor nurse captures the error. Another woman receives a rapid infusion of magnesium sulfate postpartum instead of oxytocin, despite staff awareness of prior mix-ups.

In many cases, events like these continue to happen in hospitals with drugs that are on the hospital's list of high-alert medications. The Institute for Safe Medication Practices (ISMP) defines high-alert medications as drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. This is repeatedly borne out in the literature[1–5] and by reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP). High-alert medications top the list of drugs involved in moderate-to-severe patient outcomes when an error happens.[1–2]

The Joint Commission has a standard (MM.01.01.03) that requires hospitals to develop their own list of high-alert medications; to have a process for managing high-alert medications; and to implement that process. While most facilities meet the minimum requirements for The Joint Commission (i.e., any list, any process), some hospitals have neither a well-reasoned list of high-alert medications nor a robust set of processes for managing the high-alert medications on their list. Instead, they have a hastily devised list of high-alert medications, which often are not well known to all clinicians, and they may rely on low-leverage risk-reduction strategies to prevent errors, such as staff education and high-alert medication labels on pharmacy bins, to keep patients safe. The hospital may also send memos to staff to increase their awareness of the risks or establish strategies that impact only one aspect of the medication-use process—usually drug storage. In some cases, there are no safety nets in place at all, and hospitals are relying on staff vigilance to keep patients safe when receiving high-alert medications. In addition, some hospitals have not updated their list of high-alert medications since it was first mandated by The Joint Commission more than 10 years ago. A list of high-alert medications is relatively useless unless it is up to date, known by clinical staff, and accompanied by robust risk-reduction strategies more effective than awareness, manual double checks, staff education, and appeals to "be careful." Many of these strategies should be translated for use with other medications.

So, what does it mean if a drug is on your hospital's high-alert medication list? Does the list serve only to increase awareness of the risk of harm with these medications, or has a robust plan been implemented for each drug or drug class to reduce the risk of errors? Hospitals need a well-thought-out list of specific, high-alert medications and effective high-leverage processes to mitigate the risk of errors with these medications.

SAFE PRACTICE RECOMMENDATIONS

We encourage hospitals to take the time to reassess their current list of high-alert medications and any plans that have been enacted to reduce the risk of errors and harm with these drugs. To guide this process, please consider the following:

Develop or Update a Hospital-Specific List

Hospitals need a list of targeted high-alert medications that is comprehensive enough to address the most potentially harmful errors while not being so inclusive that the list is overwhelming. Many hospitals select medications from ISMP's *List of High-Alert Medications* (www.ismp.org/Tools/institutionalhighAlert.asp), which is updated every few years based on error reports submitted to ISMP MERP, reports of harmful errors in the literature, and input from practitioners and safety experts.[4] Based on national reports of harm to patients, we believe it is essential for every hospital's list to include (when used): concentrated electrolytes, neuromuscular blocking agents, opioids (all, not just patient-controlled analgesia), anticoagulants, insulin, epidural or intrathecal medications, and chemotherapy. Other drugs from the ISMP list should be added if use is prevalent or misuse is a concern.

Additional medications to consider for the list may include new drugs added to the formulary, potentially harmful drugs used temporarily during a shortage (which can be removed once the shortage is over), and medications involved in potentially harmful errors based on the hospital's internal reporting process, even if the drug is not on the ISMP list. For example, after fatal wrong-route errors were identified as a

Table 1 Key Safety Strategies for Safeguarding High-Alert Medications

Key Strategies	Description	Examples
FMEA and self-assessments	Proactively identify the ways that processes or medication-related equipment can fail, why it might fail, how it might affect patients, and how it can be made safer; assess current systems and practices against best practices	• Perform an FMEA on a new high-alert medication before initial use • Perform an FMEA on a new infusion pump being considered for purchase (see ISMP FMEA tool: www.ismp.org/Tools/FMEA.asp) • Perform an FMEA on a high-risk process associated with medication use • Perform an FMEA on the use of alternative medications during a drug shortage
Forcing functions and fail-safes	Employ procedures or equipment design features that will: • Prevent something from happening until certain conditions are met (forcing function) • Prevent malfunctioning or unintended operation by reverting back to a predetermined safe state if a failure occurs (fail-safe)	• Use of oral syringes that cannot be connected to IV tubing ports • Use of epidural tubing without ports • Use of infusion pump sets with an automatic clamping mechanism to prevent free-flow if the tubing is removed from the pump • Engineering features that stop a process from moving forward or require the entry of key information (e.g., allergies) before proceeding
Limit access or use	Use constraints to restrict access to certain medications or error-prone processes; require special education or conditions for prescribing, dispensing, or administering a particular drug; require special authorization for participation in certain tasks	• Sequester neuromuscular blocking agents in separate containers or a locked, lidded ADC drawer to limit access • Require special education/credentialing for the ordering, preparation, and use of certain high-alert medications (e.g., chemotherapy) • Carefully select the drugs, concentrations, and quantities of medications in floor stock/ADCs • Establish parameters to change IV therapy to oral therapy as soon as possible to limit IV access • Limit the administration of certain medications unless certain criteria are met (staffing, monitoring)
Maximize access to information	Use active, not passive, means of providing staff and patients with necessary information at the appropriate time while performing critical tasks	• Use of smart infusion pumps with dose-checking software enabled • Use of concurrent data-monitoring software systems that notify practitioners with critical monitoring information (labs) • Deploy clinical pharmacists in patient care units for immediate consultation when needed • Use of electronic prescribing systems with clinical decision support, thus providing immediate warnings if unsafe orders are entered
Constraints and barriers	Use of special equipment or environmental conditions to prevent a hazard from reaching a target	• Use of personal protective equipment to reduce employee exposure to hazards • Use of a biologic safety cabinet to prepare chemotherapy • Use of a needleless system to administer medications and fluids, or for other procedures involving a potential risk of exposure from contaminated sharps
Standardize	Create clinically sound, uniform models of care or products to reduce variation and complexity	• Employ evidence-based, standard order sets (one for each care process) • Standardize concentrations, container sizes, and drugs used to treat specific conditions • Use scales that weigh patients only in kg, and document weight only in kg
Simplify	Reduce the number of steps, handoffs, and options without eliminating crucial redundancies	• Use commercially available products instead of preparing solutions • Dispense oral and parenteral medications in the most ready-to-use form • Use electronic prescribing to eliminate transcriptions • Consult dosing charts instead of manually calculating infusion rates
Externalize or centralize error-prone processes	Transfer error-prone tasks to an external site or centralized area to help ensure they are completed in a distraction-free environment by those with expertise, with appropriate quality-control checks in place	• Use commercially available products • Have a centralized pharmacy IV admixture service prepare all IV solutions under sterile conditions as specified in USP <797> • Use a specialized external service (outsourcer) to prepare complicated solutions, such as parenteral nutrition or cardioplegic solutions

ADC = automated dispensing cabinet; FMEA = failure modes and effects analysis; ISMP = Institute for Safe Medication Practices; IV = intravenous.

potential threat with the new drug Exparel (bupivacaine liposome injectable suspension, Pacira Pharmaceuticals), which is used for local anesthesia to surgical sites, due to its similar appearance to propofol,[6] hospitals that added this drug to their formulary should have considered it for addition to their high-alert medication list. Addressing drugs given by a certain route of administration (e.g., intrathecal, epidural) or in special populations (e.g., pediatrics) as high-alert can be effective as well. The hospital's high-alert medication list should be updated as needed and reviewed at least every two years.

Implement Risk-Reduction Strategies

The purpose of identifying high-alert medications is to establish safeguards to reduce the risk of errors with these drugs in all phases of the medication-use process. The primary goals of implementing risk-reduction strategies are to: 1) prevent errors, 2) make errors visible, and 3) mitigate harm. To be effective, all of these interdisciplinary components are needed:

Understand the causes of errors. Effective strategies must address the underlying causes of errors with each type of high-alert medication or class of medications. To learn the causes of errors, review internal medication error-reporting data and the results of any applicable root cause analyses. Equally important, a search of the external literature should be completed to uncover reports of errors with high-alert medications that have occurred elsewhere. A failure modes and effects analysis or self-assessment tool also might help identify underlying risks associated with each high-alert medication/class of medications. This important first step should not be skipped—if you can't describe the ways that errors have happened or could happen with the drug, your strategies may not lessen the risk of an error at all.

Be sure actions are comprehensive. A single risk-reduction strategy for each high-alert medication is rarely enough to prevent harmful errors. The keys to success are as follows:

1. Numerous risk-reduction strategies must be layered together to address the targeted risk.
2. Risk-reduction strategies should impact as many steps of the medication-use process as feasible given the underlying causes (e.g., procuring, storing, prescribing, transcribing, preparing, dispensing, and administering the medication; monitoring the patient; being prepared for treating [or recovery from] an adverse event if it occurs).
3. Low-leverage risk-reduction strategies such as staff education, passive information, and the use of reminders should be bundled together with high-leverage risk-reduction strategies such as forcing functions and fail-safes, maximizing access to information, limiting access or use, constraints and barriers, standardization, and simplification. Table 1 provides a description of key risk-reduction strategies listed roughly in descending order of effectiveness based on human factors. We highly encourage hospitals to reference this table whenever risk-reduction plans are being developed.
4. To help inform the planning process, the literature should be searched to identify risk-reduction strategies that have been proven effective, recommended by experts, or implemented successfully elsewhere.
5. Strategies need to be applicable in various settings.
6. When implementing strategies, there must be a balance on how resources will be impacted by the change.
7. Strategies must be sustainable over time.

Assess the Effectiveness of Strategies

Both outcome and process measures should be established, and data should be collected routinely to determine the effectiveness of risk-reduction strategies for high-alert medications. The results should be shared regularly in meetings with pharmacy and nursing leadership, the medication safety committee, the P&T committee, and other appropriate committees. Reviewing the effectiveness of safeguards and extending the reach of all of your risk-reduction strategies are important to ongoing success within your organization.

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The reports described in this column were received through the ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP website (www.ismp.org) or communicated directly to ISMP by calling 1-800-FAIL-SAFE or via email at ismpinfo@ismp.org. ■